

REMARKS

Claims 13-14 and 34-50 are pending in the application.

Claim 13 has been amended to no longer include the recitation “flows”. Support for the amendment is to be found in the specification at page 9, paragraph [43] that recites “a thermal exchange composition disposed within the reservoir”.

Claim 34 has been amended to include the limitation of the balloon having “a longitudinally disposed groove upon its outer surface” as recited in originally filed claim 12.

No new matter has been added by these amendments. Applicants respectfully request entry of the present amendments.

Claim Rejections under 35 USC § 112, second paragraph

1) The Examiner has rejected claims 13-14 and 37-50 under 35 USC § 112, second paragraph as being indefinite. The Examiner stated that it was unclear in claim 13 how the thermal exchange composition can “flow” if it is selected from a group consisting of a solid or a gel. The Examiner stated that correction is required.

Applicants have amended claim 13 to recite “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, further comprising a third elongate tubular body 3 having a proximal end and a distal end, the third elongate tubular body disposed longitudinally within the second elongate tubular body, and wherein the balloon is sealably affixed to the outer surface of the first elongate tubular body and sealably affixed to the outer

surface of the third elongate tubular body, the lumen 8 further comprising a thermal exchange composition, wherein the thermal exchange composition is disposed within the continuous fluid pathway formed by the second elongate tubular body 2, the first elongate tubular body 1, and the balloon lumen 8 and wherein the thermal exchange composition is selected from the group consisting of a solid, a gel, a liquid, and a gas, (d) a transducer 29, and wherein the balloon, when inflated has a longitudinally disposed groove upon its outer surface and is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants submit that claim 13 as amended now recites that the thermal exchange composition is disposed within the continuous fluid pathway and that claim 13 as amended is no longer indefinite.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 13-14 and 37-50 under 35 USC § 112, second paragraph, as being indefinite.

Claim Rejections under 35 USC § 103(a)

2) The Examiner has rejected claims 13, 14, 34-41, and 45-50 under 35 USC § 103(a) as being unpatentable over Stull (USPN 7,077,825) in view of Joye et al. (USPN 5,972,979).

3) The Examiner stated that Stull discloses the catheter, transducer, marker, and balloon structure of claim 13 except for the longitudinally disposed groove on the outer surface of the balloon and a guidewire lumen. However, the Examiner continued, Joye et al. discloses a cooling balloon catheter with a guidewire and a guidewire lumen which is well-known in the art.

The Examiner then stated that, therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Stull, as taught by Joye et al. to provide a third elongate tubular body as claimed which is a guidewire lumen.

The Examiner then stated that, regarding the longitudinally disposed groove on the outer surface of the balloon, the Examiner maintained that a typical heat exchange catheter balloon (flexible and pliable) can be partially inflated as required to form a groove as the balloon conforms to the shape and size of a similarly shaped anatomical structure.

“The question of obviousness depends . . . on ‘not only what the references expressly teach, but what they would collectively suggest to one of ordinary skill in the art.’” *Leinoff v. Louis Milona & Sons*, 220 USPQ 845, 848-49 (CAFC 1984) (quoting *In re Simon*, 174 USPQ 114, 116 (CCPA 1972)).

In determining whether a prima facie showing of obviousness exists, it is necessary to ascertain whether the prior art teachings are sufficient to suggest the claimed invention to one of ordinary skill in the art [*In re Clinton*, 527 F.2d 1226, 188 USPQ 365 (C.C.P.A. 1976); *In re Lalu*, 747 F.2d 703, 705, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984);]. This burden, which is entirely upon the Patent Office, can only be met:

by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references [to produce the claimed invention]. [Emphasis supplied]

In re Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In re Lalu*, *Supra*].

"Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself." *In re Rinehart*, 189 USPQ 143, 147 (CCPA 1976). {Piasecki, Eli Lilly}

The legal standards for establishing a prima face case of obviousness is well-established and clearly set out in the MPEP at 706.02(j) and 2141:

Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

(A) Ascertaining the differences between the claimed invention and the prior art; and

(B) Ascertaining the differences between the claimed invention and the prior art; and

(C) Resolving the level of ordinary skill in the pertinent art
Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

Applicants respectfully submit that the Examiner has not provided objective teaching that a typical heat exchange catheter balloon (flexible and pliable) can be partially inflated as required to form a groove as the balloon conforms to the shape and size of a similarly shaped anatomical structure. Applicants submit that the Examiner has not shown that these assertions would have a reasonable expectation of success.

Applicants herewith provide evidence in the form of a Declaration under 37 CFR § 1.132 (“Declaration”) by one of the named inventors of the instant application, Dr. Elizabeth Dzeng. Dr. Dzeng is a physician with particular clinical experience in the field of non-invasive cooling and is familiar with the human anatomy, particularly in regards to the structures of passageways (see Declaration at pages 1-2, section 2).

Dr. Dzeng provides rebuttal evidence that the Examiner’s assertion that “a typical heat exchange catheter balloon (flexible and pliable) can be partially inflated as required to form a groove as the balloon conforms to the shape and size of a similarly shaped anatomical structure”. Dr. Dzeng states that “I know of no anatomical structure into which the heat exchange catheter system of the invention would be placed that could in any way cause a groove to form in the balloon as suggested by the Examiner” (see Declaration at page 2, section 4).

Applicants submit that the Examiner has not shown that the teachings collectively suggest to one of ordinary skill in the art or that any objective teaching in the prior art or

that knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teachings of the references that would result in the formation of a groove as the partially inflated balloon conforms to the shape and size of a similarly shaped anatomical structure. As evidence, Dr. Dzeng contends in the Declaration that the balloon device of Stull, even when partially inflated, could not form a groove as the balloon conforms to the shape and size of a similarly shaped anatomical structure (see Declaration at page 3, section 5).

Dr. Dzeng also states that the Examiner's assertion that the balloon device of Stull can be partially inflated as required to form a groove as the balloon conforms to the shape and size of a similarly shaped anatomical structure in fact teaches away from one object of the invention, which is to allow swallowing by the patient, and that a partially filled balloon conforming in shape and size of an anatomical structure would result in blockage of said structure (see Declaration at page 2, section 4).

In summary, Applicants have provided facts established by rebuttal evidence and further believe that the Examiner has not provided objective teaching in the prior art or knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant teachings to produce the claimed invention.

Applicants submit that claim 13 is not unpatentable over Stull in view of Joye et al.

Applicants submit that rejected claims 14, 37-41 and 45-50 are dependent upon claim 13 and therefore, with the disqualification of Stull as prior art 35 USC § 103(a), claims 14, 37-41 and 45-50 are therefore not unpatentable over Stull in view of Joye et al.

Applicants respectfully request that the Examiner withdraw the rejection of claims 13, 14, 37-41, and 45-50 under 35 USC § 103(a) as being unpatentable over Stull (USPN 7,077,825) in view of Joye et al. (USPN 5,972,979).

4) The Examiner stated that, further to claims 34-36, Stull discloses the method essentially as claimed, wherein the cooling rates could obviously be determined by a skillful artisan without undue experimentation.

Applicants have amended claim 34 to recite “A method of altering the temperature of the myocardium of the heart in a subject, the method comprising the steps of: placing a heat exchange catheter system into the esophagus of a subject, wherein the heat exchange catheter system is adapted for placement within an anatomical structure of a subject, and comprises (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a transducer 29, (d) a marker 31, (e) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, further comprising a thermal exchange composition within balloon lumen 8, wherein the thermal exchange composition flows within the continuous fluid pathway formed by the second elongate tubular body 2, the first elongate tubular body 1, and the balloon lumen 8, and wherein the balloon, when inflated, has a longitudinally disposed groove upon its outer surface and is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled; and circulating the thermal exchange composition within the continuous fluid pathway, whereby the myocardium of the heart is cooled”.

Applicants submit that claim 34 as amended does not recite the disclosed method of Stull and request that the Examiner withdraw the rejection of claim 34 35 USC § 103(a), as being unpatentable over Stull in view of Joye et al.

Applicants submit that rejected claims 35 and 36 are dependent upon claim 34 and therefore, with the disqualification of Stull as prior art 35 USC § 103(a), claims 35 and 36 are therefore not unpatentable over Stull in view of Joye et al.

Applicants respectfully request that the Examiner withdraw the rejection of claims 34-36 under 35 USC § 103(a) as being unpatentable over Stull (USPN 7,077,825) in view of Joye et al. (USPN 5,972,979).

6) The Examiner has rejected claim 42 under 35 USC § 103(a) as being unpatentable over Stull (USPN 7,077,825) and Joye et al. (USPN 5,972,979) as applied to claim 13 and further in view of Knowlton (USPN 6,427,098).

With the disqualification of the Stull reference as relevant prior art as argued above, as applied to claim 13, Applicants submit that dependent claim 42 is therefore not unpatentable over Stull and Joye et al. in view of Knowlton.

Applicants respectfully request that the Examiner withdraw the rejection of claim 42 under 35 USC § 103(a).

CONCLUSION

With the above amendments and additional remarks, Applicants submit that the instant application is now in condition for allowance.

If the US Patent Office believes that communication would further the prosecution of this application, then the appropriate US Patent Office personnel are invited to contact the Applicants' below-signed representative at their earliest convenience.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Bell & Associates Deposit Account No. 50-3194.

Dated and signed:

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